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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,639	02/28/2002	Donald J. McMichael	KCX-518B (17507B)	5371

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STEPHEN E. BONDURA, ESQ.  
DORITY & MANNING, P.A.  
P.O. BOX 1449  
GREENVILLE, SC 29602-1449

EXAMINER
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FOSTER, JIMMY G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/085,639

Applicant(s)

MCMICHAEL ET AL.

Examiner

Jimmy G Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-10 is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 11-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 20 August 2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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1) It is noted that some claims which previously were considered to include allowable subject matter have been reviewed with respect to the prior art and have been found to be unpatentable for reasons set forth in some of the following rejections with respect to those claims.

2) Claims 8-10 are allowable.

3) Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation calling for the container to cover a recess in a second planar surface is not supported in the original disclosure. The first disclosed surface is 64. The second disclosed surface is 66. The container 24 is not disclosed as covering any of the recesses in second surface 64. Accordingly, claims 3 and 4 include new matter.

4) Claims 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the articles set forth in line 20 of claim 1 relate to the articles positively introduced as structure in line 3 of claim 1.

5) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6) Claims 1 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Paikoff et al (4,523,679). In the reference of Paikoff et al, there is provided a tray 14. The tray includes a first planar surface which includes recesses therein for holding the fluid sampling means 21 and syringes 18 and sponge scrubbers 16. There is a second planar surface, vertically offset from the first planar surface, which includes recesses for holding sheath caps 18' and 20'. There is a third planar surface, vertically offset from the first and second surfaces, which includes recesses for holding the vial 26. And there are further surgical articles, such as the drug transfer means 19, the patient covering means and the bandage means 23 which are located in the overall recess of the tray 14 and which cover other ones of the articles already mentioned.

Although Applicant both positively recites surgical articles in the claims and claims a limitation calling for the planar surfaces to all be at least partially outside the perimeter of one another, Applicant fails 1) to clearly claim that the surgical articles are in the recesses and 2) to claim that the articles which were recited in a structural fashion are the ones in the recesses. While none of the articles 19, 22 and 23 of Paikoff et al are located in a recess which meets the limitation calling for the planar surfaces to all be at least partially outside the perimeter of one another, any of the recesses for articles 16, 18, 21 or 26 is capable of instead holding an article (not disclosed by the reference) which could extend out of

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its recess and over and across other recesses. This capability meets Applicant's changed and added limitations.

In addition, there is a wrapper cover 10 or 28 provided over the tray (see Fig. 1A,4).

Accordingly, Applicant's claimed subject matter does not distinguish over the disclosure of Paikoff et al.

7) Claims 11-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ross et al (5,318,543). The kit tray 13 of Ross includes planar surfaces at three different locations: (1) a first surface including the recess for holding the syringes 17 and 27, (2) a second surface which includes the recess that receives the sheathed needle 16, and (3) a surface which includes the recess for holding scalpel 15. There is also a surface defined by the peripheral lip of the tray, which includes a recess defined by the entire interior of the tray.

The reference also discloses a container at pouch 20. The container 20 fits within the tray 13 and rests upon said first surface (indicated above, which has the recess for syringes 17 and 27). This location of the container is such that it fully covers the recesses of the surface.

However, Applicant associates each of Applicant's recesses with the lowest planar surface which meets the periphery of the recess. For example, this is done with Applicant's recesses 76 which are said to be in the planar surface 64, not in the planar surface 68 or 70. Using this same standard, the recess of Ross et al for holding the dilator 29 may be said to be in the planar surface which also includes recesses for syringes 17 and 27. This is

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apparent from Figure 3 of the reference. Accordingly, the container 20 of Ross et al may be said to rest on said first planar surface while leaving a recess (for dilator 29) in that planar surface exposed.

Regarding Applicant's limitation with respect to the container being adapted to be reclosed, the pouch/container 20 of Ross et al is inherently reclosable after it is opened (for example by a knife), even if the reference does not disclose reclosing the container. Some ways to reclose the container are adhesive, heat sealing and clips.

The recesses of the tray of Ross are inherently capable of holding the articles claimed by Applicant as intended use (and not structure) in claims 11-19.

The tray is covered in the manner shown in Figure 1.

8) Claims 3, 20 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kalinski (5,311,990). In the reference of Kalinski there is provided a first planar surface at shoulder 95, circumscribing a recess in which an article/container 55 is received. In addition, there is a second planar surface at floor 85 which includes a recess for holding a cord/article near the center of the tray. There appears to be third planar surface defined by the tops of the pedestals which hold the gun-shaped article between them. The gun-shaped article rests in a recess of the third surface, between said pedestals.

The container/article 55 is intended to be located over the other articles of the tray such that the other articles cannot be accessed until the container/article is removed from the tray. The reference discloses

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that the package is intended to be adapted to contain instruments/articles for a surgical procedure.

A cover is provided at 25.

Regarding Applicant's claim 20, which calls for the container to be adapted to at least partially fit in the tray and to be adapted to rest on one of the planar surfaces while exposing a least one of the recesses in the surface, there is no positive structural recitation that the container is located in the tray while being supported on the planar surface while also exposing the at least one recess of the planar surface. Although not disclosed for such use, the tray 55 of Kalinski is capable of fitting only partially within the tray 80 such that it may rest its one end on the planar surface 95, intermediately of the extent of the planar surface, while extending partially out of the tray and have its other end raised from and beyond the end of the tray, in a manner such that the container 55 does not cover the entire recess that is defined by the surface 95. Thus, the recess of surface 95 would be exposed. The cover 25 is adapted to be placed over the tray, but the cover is also adapted to close the container 55. Regarding the limitation calling for a boss, any of the portions of the tray bottom of Kalinski that are raised above the planar surface on which the gun-shaped element rests, may be considered to define a boss. The container 55 also holds medical devices. The surface 95 is offset generally radially from the remainder of the tray and therefore from the other planar surfaces. Surface 95 is also vertically offset from the other planar surfaces.

In a like manner with Applicant's claim 3, the container 55 of Kalinski is adapted to fit partially within the tray 80 such that it may rest its one

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end on the planar surface 95 while extending partially out of the tray so as to have its other end raised from and extend beyond the end of the tray, in a manner such that the container 55 does not cover the entire recess that is defined by the surface 95. In Figure 1 of Kalinski there is shown two similar rectangular recesses (unnumbered) on either side of a raised portion. It is possible to situate the container 55 on the planar surface 95 in the manner herein described such that a portion of the recess of planar surface 95 is accessible while the container 55 remains vertically over one of the said two rectangular recesses. Accordingly, the container 55 is capable of providing access to the recess of the planar surface 95 while covering the said rectangular recesses of the second surface.

9) The combination set forth in claim 4, although including new matter, distinguishes over the prior art.

10) Claims 6 and 7 would be allowable if appropriately rewritten to overcome the rejection under 35 U.S.C. § 112 (by relating the articles set forth in line 20 of claim 1 to the articles introduced in line 3 of claim 1) and to include all of the limitations of the base claim.

11) Applicant's arguments filed June 30, 2004 have been fully considered but they are not deemed to be persuasive. Applicant fails to clearly claim that the surgical articles are in the recesses in claim 1, and Applicant fails to claim that the articles which were recited in a structural fashion in claim 1 are the ones in the recesses. Any of the recesses for articles



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16, 18, 21 or 26 of Paikoff is capable of holding a different article (not disclosed by the reference) which could extend out of its recess and over and across other recesses. This capability meets Applicant's changed and added limitations.

Regarding claim 3, 20 and 21, unlike claim 1, these claims do not call for each of the planar surfaces to be partially outside the perimeter of the other surfaces. The container 55 of Kalinski is capable of being disposed on the surface 95 in a manner to leave access to a the recess defined by the surface in the manner as set forth in the rejection, so as to provide access to a recess in the surface 95.

Regarding the rejection of claim 11-19, the recess of Ross et al for holding the dilator 29 is considered to be partially defined in the surface on which the container 20 rest. Although claim 11-19 structurally call for the container to be disposed on a planar surface, the description of the recesses in Applicant's specification associates each recess with the lowermost planar surface at the perimeter of that recess. Accordingly the exposure of the recess for holding the dilator 29 of Ross et al meets what Applicant has claimed regarding a recess in the planar surface being exposed.

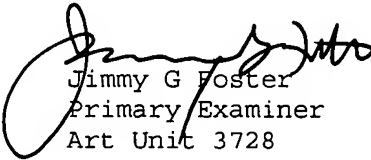
12) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy G Foster whose telephone number is (703) 308-1505. The examiner can normally be reached on Mon-Fri, 8:45 am - 5:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (703) 308-2672. The fax

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phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

  
Jimmy G Foster  
Primary Examiner  
Art Unit 3728

JGF  
27 September 2004